



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 28 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Registrant Response to Deficiencies in Support of the Registration of B2E-10, Containing 1.80% (S)-Methoprene [Isopropyl (2E,4E,7S)-methoxy-3,7,11-trimethyl-2,4-dodecadienoate] As Its Active Ingredient.

End-Use Product (EP) Registration No.: 75318-RN

Active Ingredient (AI) PC Code: 105402, [REDACTED]

DP Barcode: 327778

Decision No.: 365256

MRID No.: N/A

FROM: Angela L. Gonzales, Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in blue ink, appearing to read "Angela L. Gonzales", is written over the typed name in the "FROM:" field.

TO: Mari Duggard, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

B2E Biotech LLC requests registration of B2E-10 (EPA Reg. No. 75318-?), an end-use product (EP) containing 1.80% (S)-Methoprene [Isopropyl (2E,4E,7S)-methoxy-3,7,11-trimethyl-2,4-dodecadienoate], an insect growth regulator (IGR), as its active ingredient. The source of the technical grade of the active ingredient (TGAI), is registered with the Agency; EPA [REDACTED] This product is intended for use to control mosquitoes in breeding areas. In support of registration, the registrant submitted a Confidential Statement of Formula (CSF) dated 9/14/05, a proposed product label, product chemistry data in MRIDs 46766301 through 46766305, efficacy data in MRIDs 46766306 and 46766307, acute toxicity waiver rationale in MRID 46766308 and estimated environmental concentration (EEC) data in MRID 46766309. Deficiencies with the submission were provided to the registrant via email and telephone correspondence on June 21, 2006, to which the registrant replied in an email message dated June 22, 2006. This memorandum is a review of the registrant's reply to addressed deficiencies.

~~THE FOLLOWING PAGES CONTAIN CONFIDENTIAL BUSINESS INFORMATION~~

RECOMMENDATIONS AND CONCLUSIONS

Product Chemistry- **ACCEPTABLE**, pending resolution of deficiencies listed below.

1. In box 10 of the CSF, the registrant must provide the description of the manufacturing-use product (MP) as: "B2E-06, containing 40.0% Isopropyl (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate; CAS No. 65733-16-6".
2. The registrant must consistently list the concentration of the active ingredient on the CSF and on the label. The registrant must change the concentration of the active ingredient on the label to 1.80%, to match the concentration on the CSF.

Product Performance- **ACCEPTABLE**, pending label revisions addressed below.

1. Submitted efficacy data do not support the statement, "Use higher rates when water is deep [$>2\text{ft}$] and when vegetation and/or organic matter is heavy". This statement must be removed from the label. Submitted data only support EP application to water depths that are less than or equal to two feet.
2. Submitted data support pre-hatch treatments to dry sites up to 3 days prior to flooding. It is noted that a 7-day pre-hatch treatment was effective in mosquito control. However, replicates of this experiment were not provided to verify the data.

Note to RAL:

1. The statement "...and/or more frequent applications" within the statement on the label, "Application of B2E-10 to sites subject to water flow or exchange will diminish the product's effectiveness and requires higher application rates and/or more frequent applications within the ranges of the use rates specified" is too broad and may lead to over-treatment, which would effect EEC concentrations of the TGAI as depicted in MRID 46766309.

STUDY SUMMARIES

Product Chemistry

Amended product chemistry data to rectify the typographical errors discussed in the memorandum from A. L. Gonzales to M. Duggard dated June 15, 2006, were submitted in the email correspondence and are adequate. CSF revisions are adequate with the exception that the description of the MP in box 10 of the CSF must be reworded. The concentration of the TGAI on the CSF and label must be the same.

Product Performance

MRID 46766306 was amended based on the raw data by the registrant to include pre-hatch and water depth area. Pre-hatch treatments were performed at 4 days, 7 days and 3 days (3 replicates were used for the 3-day pre-hatch experiment), and all treatments resulted in adequate control. Based on the lack of replicate experiments for the 7-day study, submitted data support pre-hatch treatment claims for up to 3 days only. The registrant's rationale for extending the pre-hatch treatment claim to 14 days by bridging data from the MP is inadequate because the EP is manufactured using the MP and the EP was used as the test material used during the efficacy studies. Water depths during the experiments ranged from 6 inches to 24 inches. The registrant stated that average water depths of the microcosms used in MRID 46766307 were calculated by converting the number of gallons in each plot (approximately 16 gallons) to cubic feet and then dividing by the surface area (4.36 ft²). Depths were reported to be approximately 6 inches.

cc: A. Gonzales, M. Duggard, BPPD Subject File, IHAD/ARS
A. Gonzales, FT, PY1, 06/28/2006